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Contact Person - Cort Jensen (406) 444-5439

The Governor's Consumer Protection Office Joins 50 Consumer Protection Officials and Attorneys General in a Historic Settlement Resolving an Investigation of Improper Off-Label Drug Marketing by Warner-Lambert

The Governor's Consumer Protection Office, today announced a nationwide Consumer Protection settlement with Warner-Lambert (a wholly owned subsidiary of Pfizer Inc. – the world's largest pharmaceutical company) resolving allegations of deceptive "off-label" marketing of the blockbuster drug – Neurontin©. In settling this consumer protection investigation, Warner-Lambert will pay the states a total of $38 million.

This settlement of state consumer protection claims is part of an unprecedented global 50 state settlement being announced today that also resolves investigations by the National Association of Medicaid Fraud Control Units and the U.S. Attorney's Office out of Boston. In total, Warner-Lambert will pay $430 million under these settlements.

The consumer protection investigation focused on alleged violations of state consumer protection laws that occurred when Warner-Lambert promoted Neurontin for various "off-label" indications – including various psychiatric disorders, back pain, and headache – even though the scientific evidence supporting the use of Neurontin for these indications was lacking. Neurontin is a prescription medication approved by the Food and Drug Administration ("FDA") for adjunctive treatment of epilepsy and treatment of post-herpetic neuralgia. Approximately 90% of Neurontin prescriptions, however, are for off-label purposes.

It is illegal for pharmaceutical manufacturers to promote the off-label use of their drugs, although doctors are permitted to prescribe for such uses. Warner-Lambert engaged in off-label promotion of Neurontin in a variety of ways, dramatically increasing the prescribing of Neurontin for off label indications for which there is little or no scientific evidence of efficacy.

Among the methods used by Warner Lambert to deceptively promote Neurontin for off-label indications were:

- continuing medical education classes ("CMEs") that lacked fair balance and misrepresented the nature of the CME and provided expensive "perks" to attending physicians;
- a "publication strategy" that subsidized the production and dissemination of anecdotal reports favorable to off label use of Neurontin and were of no scientific value;
- payments to prescribers for "research" that was, in effect, a kickback for off-label prescribing; and,
- providing incomplete information about Neurontin to the drug reference compendium "Drugdex."

The settlement, by an Assurance of Voluntary Compliance or Discontinuance prohibits Warner-Lambert and its corporate parent Pfizer Inc. from the following activities:

- making false, misleading or deceptive oral or written claims about Neurontin and from promoting off-label uses in violation of the federal Food, Drug and Cosmetic Act;
- misrepresenting the nature of scientific evidence relating to Neurontin;
- disseminating written materials that have not appeared in peer reviewed scientific journals in contravention of limitations set forth in the Assurance;
- failing to make disclosures about funding of research and educational events related to Neurontin;
- failing to require speakers at educational events related to Neurontin who have financial relationships with Warner Lambert or Pfizer from disclosing their relationship, including whether the speaker has been paid to promote Neurontin;
- failing to comply with the Pharmaceutical Research and Manufacturers of America Code with respect to payments, gifts and remuneration to health care providers (compliance with this Code has previously been voluntary);
- failing to comply with Accreditation Council for Continuing Medical Education Guidelines (compliance with the Guidelines has previously been voluntary);
- misrepresenting the credentials of sales, medical and technical personnel;
- providing information that is misleading or lacking in fair balance to drug reference compendia; and,
- violating Federal anti-kickback laws.

Of the $38 million provided under the consumer protection settlement, $28 million will be used in a remediation program and a total of $10 million will be distributed to the participating Consumer Protection's offices to be used for attorney's fees and other costs of investigation. Montana's share of the payment for attorney's fees and costs will be $278,000.

Under the remediation program, up to $6 million of the fund will go toward a National Advertising Program to provide physicians and other prescribers with fair and balanced information about Neurontin and other drugs in its therapeutic class. At least $21 million will be used to fund a Prescriber and Consumer Education Program, which will make grant monies available to governmental entities, academic institutions, and not-for-profit organizations that provides prescribers and/or consumers with fair and balanced information about drugs. Finally, up to $1 million of the fund will be utilized to evaluate the effectiveness of the remediation program.